

EXHIBIT D

Expert Report of Elizabeth Akhparyan Park, Pharm.D., APh, in
Rebuttal

January 21, 2022

The City & County of San Francisco, et al. v. Purdue Pharma L.P., et al.
Case No. 3:18-cv-07591-CRB

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I. Qualifications

I submitted an expert report in this matter on October 19, 2021 (“Park Report”). My qualifications are set out in Part I and Appendix A of that report and remain unchanged.

II. Materials Considered

In addition to the materials listed in Appendix B of the Park Report, the opinions in this report are based on my professional experience as well as on my review of the materials listed in Rebuttal Appendix A below.

III. Assignment

I have been asked (1) to respond to the critiques of the Park Report contained in the expert reports of Dr. Kathleen Hill Besinque (“Besinque Report”) and Dr. Robert L. Brunner (“Brunner Report”) submitted in this matter on December 2, 2021; and (2) to review additional patient history files from the approximately 2,300 prescriptions I reviewed for the Park Report, and determine whether the Besinque and Brunner Reports are right to conclude that Walgreens’s patient history files document resolution of “red flags” under the California standard of practice. This Rebuttal Report further addresses certain evidence that was not available when I submitted the Park Report, including the depositions of several former and current Walgreens pharmacists,¹ as well as the inspection of the current Walgreens pharmacy software system that I attended on January 12, 2022.

IV. Summary of Rebuttal Opinions

If called to testify at trial, I intend to offer the following opinions in rebuttal, which I hold to a reasonable degree of professional certainty:

1. California pharmacies and pharmacists are responsible for complying with the applicable standards of practice in deciding whether and how to dispense opioids, including those standards not contained in a written statute or regulation.
2. There is overlap between the physician’s and pharmacist’s roles in California, especially in cases where opioids are prescribed.
3. The Besinque and Brunner Reports’ critiques of my analysis of approximately 2,300 prescriptions produced by Walgreens contained in the Park Report are misplaced and do not alter my opinions stated in the Park Report.
4. Walgreens’s patient history files do not consistently document identification and resolution of red flags, and do not materially change my analysis of the approximately 2,300 prescriptions produced by Walgreens contained in the Park Report.

¹ The pharmacists are Christy Mathews-Porter, Rebecca Gayle, Jeremy Gerspacher, Robert Yagar, and Golnaz Kamali.

5. The Besinque Report's other critiques of the Park Report are unsupported, self-contradictory, or irrelevant.

V. Rebuttal Opinion 1: California Pharmacies and Pharmacists Are Responsible for Complying With the Standard of Practice, Even if the Standard Is Not Contained in a Written Statute or Regulation.

In the Park Report, I summarize the standards of practice applicable in California to pharmacists' and pharmacies' opioid dispensing practices and apply them to 16 predefined "red flags." The Besinque Report criticizes my reliance on the "standard of practice" concept and argues that, because some of the standards I identify are not contained in a written statute or regulation, they are only nonbinding guidelines or best practices.

I disagree with the Besinque Report's general suggestion that standards of practice are not binding on California pharmacies or pharmacists unless contained in a written statute or regulation. As the California State Board of Pharmacy has held, the "corresponding responsibility law"—that is, a pharmacy's and pharmacist's *legal obligation* to ensure that opioids are dispensed only for legitimate purposes—"is both a *standard of care* and a duty recognized by statute."² In deciding accusations against pharmacies and pharmacists, the Board routinely hears expert testimony to articulate the California standard of practice required in the situation that confronted the accused.³ The U.S. Drug Enforcement Administration likewise hears expert testimony on state standards of practice in registration revocation and other proceedings.⁴ If a pharmacy's or pharmacist's conduct falls below the standard of practice established by expert testimony (rather than by written statute or regulation), they may be censured by the Board⁵ (or by the DEA).⁶ In fact, at a meeting of the Board's SB 493 Implementation Committee in 2015, which Dr. Besinque attended, Committee members made clear that the Board tends to offer written guidance when there is "not a standard of practice for pharmacists"—and, by implication, that the Board is less likely to issue such guidance when the standard of practice is already well established.⁷

Specifically, I disagree with the Besinque Report's conclusion that resolution of red flags need not be documented in California because no written statute or regulation requires it. As I

² *In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran*, Board of Pharmacy Case No. 3802; OAH No. 2011010644; Precedential Decision No. 2013-01 (emphasis added). Made precedential by the Board of Pharmacy effective August 9, 2013. Available at <https://www.pharmacy.ca.gov/enforcement/fy1011/ac103802.pdf>.

³ See, e.g., *Pacifica Pharmacy*.

⁴ See, e.g., *Pharmacy Doctors Enterprises*, 83 Fed. Reg. 10876 (DEA 2018).

⁵ See, e.g., *Pacifica Pharmacy*.

⁶ See, e.g., *Pharmacy Doctors Enterprises, Inc. v. DEA*, 789 Fed. Appx. 724 (11th Cir. 2019).

⁷ California State Board of Pharmacy, Department of Consumer Affairs, SB 493 Implementation Committee, Meeting Minutes (Feb. 25, 2015).

explained in the Park Report, documentation is a widely recognized element of reasonable pharmacy practice and thus an element of the standard of practice. For further example, the California Pharmacists Association—of which Dr. Besinque was the president in 2014⁸—has published a “Corresponding Responsibility Checklist” “to help clarify the pharmacist’s *responsibility* as a member of the healthcare team.”⁹ Step 3 states as follows:

- a. The pharmacist must either resolve or not resolve every existing red flag.
- b. The pharmacist must document every resolution and non-resolution.¹⁰

The Besinque Report states, “If the pharmacist still is unable to resolve the red flag(s) after conducting such due diligence, he or she *may* decide not to dispense the medication.”¹¹ This is incorrect. The pharmacist *must not*, and has no authority to, dispense controlled substances in the presence of *any* unresolved red flags. This is demonstrated by the California Pharmacists Association’s “Corresponding Responsibility Checklist,” among other authorities.¹² The Besinque Report is also wrong to deny that California regulations do not support this position. The regulations prohibit dispensing “where the pharmacist knows or has objective reason to know” that the prescription was not issued for a legitimate purpose. An *unresolved* red flag *is* an “objective reason to know” the prescription is not legitimate.¹³

In my experience as a chief consultant who employees ten other seasoned pharmacist consultants, I have seen accusations based on alleged failures of corresponding responsibility. In these accusations, the Board has generally demanded that the accused pharmacy or pharmacist produce detailed documentation of every resolution of every red flag. Pharmacies and pharmacists that do not properly document resolution of red flags do not satisfy their corresponding responsibility and face possible revocation of their licenses.¹⁴ In a published

⁸ Given this familiarity, it is surprising to me that Dr. Besinque did not uncover or identify this checklist as part of her search of documents from “pharmaceutical organizations” for “pharmacy standards regarding documentation.” Besinque Rep. ¶ 21.

⁹ “Corresponding Responsibility Checklist,” California Pharmacists Association (emphasis added). Available at <https://www.montagehealth.org/app/files/public/0652d032-e00c-42cb-b53b-62d23c1bed62/service/pdf-prescribe-safe-corresponding-responsibility-checklist.pdf>.

¹⁰ *Id.*

¹¹ Besinque Rep. 15 (emphasis added).

¹² See, also, e.g., “Corresponding Responsibility: It’s the Law,” California State Board of Pharmacy. Available at https://www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf (discussing *Pacifica Pharmacy* and stating a “pharmacist ***must not*** fill the prescription when the results of a reasonable inquiry do not overcome concern about a prescription being written for a legitimate medical purpose”) (emphasis added).

¹³ 16 Cal. Code Reg. § 1761(b).

¹⁴ The Board is assured of proper compliance only when the Board’s consultants are able to confirm that the pharmacy and pharmacists understand the standard of practice and actually apply it in everyday practices.

paper in which Dr. Besinque appears as the second author, a group of doctors of pharmacy identifies “[d]ocument[ing] patient care activities clearly and concisely” as an “[e]ssential [e]lement” of a pharmacist’s experiential education.¹⁵ As further explained in the Park Report, Walgreens’s own policy also supports this conclusion, and states, among other things, that “[i]t is *imperative that pharmacists document all efforts used to validate good faith dispensing.*”¹⁶ This policy reflects the standard of practice. In addition, several Walgreens pharmacists whose deposition transcripts became available after I submitted the Park Report endorsed the same basic rule of pharmacy practice: If you don’t document it, it didn’t happen.¹⁷

Similarly, while I agree with the Besinque Report that no written statute or regulation necessarily requires a California pharmacist to check California’s prescription drug monitoring program, called “CURES,” I disagree with the Besinque Report that a California pharmacist is never under any factual circumstances required by the standard of practice to check CURES to fulfill her corresponding responsibility. The Park Report addresses at greater length the appropriate role of CURES in reasonable pharmacy practice in California. In the 2,300 prescription files I reviewed for the Park Report, I found many examples of red flags that were apparently not identified by Walgreens’s pharmacists because the pharmacists do not appear to have checked CURES. Additionally, the Besinque Report discusses certain triggers for a pharmacist’s investigation—such as an “opioid-naïve patient being prescribed a very high first dosage,” “doctor shopping,” and “pharmacy shopping”¹⁸—which, in general, can most effectively be identified and resolved using CURES.

In sum, in the absence of alternative sources of information, CURES may be the only way for a pharmacist to identify and resolve certain red flags. For example, in *Pacifica Pharmacy*, the accused pharmacy’s pharmacist-in-charge testified that he “did not know about the use of CURES reports for the purpose of evaluating patient therapy,” whereas the Board investigator used CURES reports to identify the pharmacy’s unlawful dispensing practices. Because the 2012 *Pacifica* decision resulted in the pharmacy and pharmacist losing their licenses, it is clear that the Board expected California pharmacists to make appropriate use of CURES well before 2016.¹⁹ Despite this, however, as I explained in detail in the Park Report, I saw evidence of repeated failures to conduct a reasonable investigation, including repeated

Additionally, the Board has often viewed evidence that an accused pharmacy or pharmacist has adopted policies and procedures stressing the importance of resolving and documenting red flags as evidence that the pharmacy or pharmacist has rehabilitated its substandard practices.

¹⁵ Jennifer Danielson & Kathleen Hill Besinque *et al.*, “Essential Elements for Core Required Advanced Pharmacy Practice Experiences,” 83 Am. J. of Pharm. Educ. 453, 456 (2019).

¹⁶ Park Rep. 19 (emphasis added).

¹⁷ Rebecca Gayle Dep. Tr. at 50-51; Christy Mathews-Porter Dep. Tr. at 72-74; Jeremy Gerspacher Dep. Tr. at 35-37.

¹⁸ Besinque Rep. 14.

¹⁹ *Contra* Besinque Rep. 5 (“CURES ... was not widely used by either prescribers or pharmacists prior to 2016.”).

failures to check CURES where appropriate.

Finally, I agree with the Besinque Report that there is no written statute or regulation specifically requiring California pharmacies to implement specific policies and procedures. I do not agree, however, with the Besinque Report's suggestion that the standard of practice does not require pharmacies to have any have policies and procedures regarding corresponding responsibility.²⁰ A pharmacy's way of exercising sound professional judgment, especially in the context of chain pharmacies like Walgreens, is to (1) implement appropriate policies and procedures; (2) enforce and audit adherence to those policies and procedures; and (3) use audit results to improve staff compliance. In my experience, I have seen the Board always look to the pharmacy's policies and procedures in any given area of practice. And to the extent the pharmacy has such policies and procedures, the Board expects full adherence to them.²¹

Specifically, in *Pacifica Pharmacy*, the Board made clear that the "corresponding responsibility law" applies to *both* pharmacies *and* pharmacists. Pharmacists and pharmacies are both required to exercise sound professional judgment when evaluating red flags. When a pharmacist is presented with questionable prescriptions, guidance must be provided by the pharmacy on how to consistently determine whether the prescription was issued for a legitimate medical purpose. This guidance comes in the form of the pharmacy's own policies and procedures. Contrary to the Besinque Report, in my experience, pharmacists do *not* receive "specialized schooling and training on how to identify and resolve red flags"²² that would substitute for or eliminate the need for proper policies and training. The testimony of several pharmacists in this case supports this conclusion.²³ In fact, California schools of pharmacy require no more than three unit hours for all of pharmacy law. Furthermore, pharmacists—even community pharmacists, and certainly pharmacists at chain retail pharmacies like Walgreens—are *busy*; they cannot reasonably be expected to "reinvent the wheel" for themselves every time they are presented with a prescription for a controlled substance. As such, in practice, pharmacists depend heavily on their employers' policies and procedures in fulfilling their corresponding responsibility. As discussed in the Park Report and further supported by recent pharmacist testimony, however, Walgreens's policies and procedures, and the training on those policies and procedures, were inadequate.²⁴

²⁰ See, e.g., Besinque Rep. 6.

²¹ See, e.g., *In the Matter of the Third Amended Accusation Against IV Solutions, Inc., et. al.* Board of Pharmacy Case No. 3606; OAH No. 2011050988; Precedential Decision No. 2020-01 ("The basis for discipline is that once ... formulated, Respondent IV Solutions had a duty to follow its own policies and procedures, but it refused to do so."). Available at https://www.pharmacy.ca.gov/enforcement/precedential/no_2020_01.pdf.

²² Besinque Rep. 5.

²³ Mathews-Porter Tr. at 133-35; Gayle Tr. at 146-47.

²⁴ See also, e.g., Gerspacher Tr. at 30-34; Gayle Tr. at 59-63 (noting that the good faith dispensing policies did not appear to be audited nor were there consistent efforts to enforce or verify compliance); Yagar Tr. at 119-26 (noting that Walgreens' training did not prepare pharmacists to deal with difficult due diligence decisions or give adequate guidance); Kamali Tr. at 58-60 (noting that Walgreens management did not support pharmacists who refused opioid prescriptions that failed the company's good faith dispensing policy). The inspection of Walgreens' current pharmacy system also provided more support for my opinion that the company does not provide pharmacists

VI. Rebuttal Opinion 2: There Is Overlap Between the Physician's and Pharmacist's Roles, Especially Where Opioids Are Prescribed.

I disagree with the Besinque Report's opinion that the physician's and pharmacist's roles do not overlap, especially where controlled substances like opioids are prescribed to the patient. These roles *must* overlap to ensure patient safety and appropriate patient care. A collaborative process is critical. In the article on pharmacy education cited above, Dr. Besinque and her co-authors identify "collaboration with other health care providers," "[a]dvocat[ing] for patient access to medications to optimize patient outcomes," and "[a]ctively contribut[ing] as a member of an interprofessional health care team" as "[e]ssential [e]lements" of a pharmacist's experiential education.²⁵

Furthermore, it is a pharmacist's job to independently evaluate a prescriber's chosen medication or treatment regimen. I specifically disagree with the Besinque Report's conclusion that "it is not the pharmacist's job or area of expertise to re-evaluate a prescriber's chosen medication or treatment regimen for the patient."²⁶ In fact, the Oath of a Pharmacist calls for pharmacists to "assure optimal outcomes for all patients,"²⁷ which would not be possible if the roles of a pharmacist and a physician did not overlap and if the pharmacist's job did not include at least periodically re-evaluating a prescriber's chosen medication. California pharmacy regulations prohibit a pharmacist from dispensing a controlled substance if the pharmacist has reason to believe it was not issued for a legitimate purpose, "[e]ven after conferring with the prescriber."²⁸ As the Board's periodical "The Script" noted, citing Health and Safety Code § 11153,²⁹ a pharmacist may "[c]ontact the prescriber to clarify or adjust a prescription" in light of corresponding responsibility concerns.³⁰ Even Dr. Besinque admits that a pharmacist cannot fill a prescription if she believes it will result in harm to the patient³¹—notwithstanding the fact that the prescriber presumably always believes their prescription order will *not* harm their patient.

adequate tools (or time) to conduct their due diligence.

²⁵ Danielson & Besinque, *supra*.

²⁶ Besinque Rep. 9.

²⁷ <https://pharmacist.com/About/Oath-of-a-Pharmacist>. The "Oath of a Pharmacist" is taken by every pharmacy student in California before graduating from pharmacy school.

²⁸ 16 Cal. Code. Reg. § 1761(b).

²⁹ At page 15 of the Park Report, I inadvertently cited Business and Professions Code § 4060 where I intended to cite this section, Health and Safety Code § 11153.

³⁰ California State Board of Pharmacy. The Script: March 2020 edition. https://www.pharmacy.ca.gov/publications/20_mar_script.pdf. The same article encourages pharmacists to "[d]iscuss with the prescriber other medications the patient is taking or other health care practitioners the patient is seeing" and to "[a]sk for documentation of a patient's medical condition, diagnosis or treatment plan."

³¹ Besinque Rep. 9.

Relatedly, the Besinque Report criticizes the Park Report's citation to this publication without including its introductory "disclaimer."³² But the "disclaimer" is entirely in accord with my opinions: *even though* a "growing number of consumers are filing complaints with the Board of Pharmacy about difficulty getting opioid prescriptions filled," it is *nonetheless* "important that pharmacists exercise their legal obligations in filling controlled substances prescriptions." The Besinque Report also omits the following relevant sentence from the same article: "Pharmacists are often the last line of defense in the battle against prescription drug abuse. As licensed professionals, they must weight their calling to serve patients against their obligations to prevent controlled substances from getting into the wrong hands."³³

VII. Rebuttal Opinion 3: The Besinque and Brunner Reports' Critiques of My Analysis of Walgreens's Due Diligence in the Park Report Do Not Change My Opinions.

I have reviewed the Besinque and Brunner Reports' critiques of my analysis of Walgreens's due diligence in the Park Report. Their critiques³⁴ are misplaced and do not change my analysis. First, much of the criticism is based on a misunderstanding or misstatement of the nature of "red flags." For example, the Besinque Report devotes a great deal of effort to coming up with hypothetical sets of facts which—if true and known to the dispensing pharmacist—would resolve a particular red flag (which resolution would still need to be documented). But these efforts do not undermine the opinions I expressed in the Park Report. I agree that the existence of a red flag does *not* mean a prescription cannot be dispensed; rather, as I explained at length in the Park Report, the existence of a red flag means the prescriptions cannot be dispensed until the pharmacist has *first resolved* the red flag after a reasonable inquiry.³⁵ The Besinque Report offers many (again hypothetical) illustrations and perhaps possible explanations for existing prescriptions, but none of these explanations is driven by any actual notes available on the records reviewed of reasonable inquiries Walgreens pharmacists *might* have performed to resolve a given red flag. For the reasons expressed in the Park Report, however, and not meaningfully contradicted by the Besinque Report, there is very little evidence in Walgreens's prescription records that such inquiries were actually performed in any consistent manner.

The Besinque Report also appears to misunderstand the nature of red flags depending on distance. The Besinque Report states, "[D]istance, however calculated, is not cause on its own to believe diversion or fraudulent activity is occurring."³⁶ Distance was expressly recognized by the Board in *Pacifica* as raising a red flag. The Board has repeatedly relied on this red flag as a basis for disciplinary action.

³² Besinque Rep. 10.

³³ California State Board of Pharmacy. The Script: March 2020 edition. https://www.pharmacy.ca.gov/publications/20_mar_script.pdf.

³⁴ I address the critiques based on Walgreens's patient history data separately below.

³⁵ In addition to the Park Report, see "Corresponding Responsibility Checklist," *supra* ("Even if one red flag is not resolved, then the pharmacist must not dispense the controlled substance.").

³⁶ Besinque Rep. 27.

Second, the Besinque and Brunner Reports criticize the Park Report on several methodological grounds, but none of their criticisms justifies revising my opinions. The Besinque Report speculates that my staff may not be licensed pharmacists, but they are. My staff consisted of three registered California pharmacists, all very experienced and in good standing with the Board, two of whom serve as Board-approved probationary consultants. Additionally, while it is correct that the opinions in the Park Report are predicated on the assumption that all 2,300 prescriptions I reviewed raised at least one genuine red flag, my team and I confirmed the accuracy of this assumption by spot-checking a statistically significant number (1,600, more than half) of the 2,300 prescriptions.

My decision not to review prescriptions where the hard copy was lacking was necessary to reach a sound conclusion as to Walgreens's due diligence, because Walgreens indicated that due diligence can be written on the hard copy. My analysis did not disregard notes fields; many of the notes fields contained data that simply did not pertain to the identification or resolution of red flags. As for the Brunner Report's complaints that I provided limited methodological detail, in the Park Report I stated my opinions and the bases for them, as I was required to do. Defendants were provided a list of the prescriptions which, in my opinion, demonstrated adequate due diligence before Defendants' expert reports were due.

VIII. Rebuttal Opinion 4: Walgreens's Patient History Files Rarely Document Resolution of Red Flags.

For the Park Report, I reviewed patient history files for 25 randomly selected prescriptions from the approximately 2,300 prescriptions for which Walgreens could locate hard copies. That review did not alter my opinions about Walgreens' due diligence failures, because (1) the prescription notes did not indicate that the pharmacists consulted the patient history before dispensing, and (2) the patient history data did not resolve all red flags raised by the prescription in any of the 25 cases.³⁷ Also, as I discussed in the Park Report, red flags often "cannot be resolved merely by reference to resolutions documented on past prescriptions," particularly for less recent patient history.³⁸ Finally, as I further mentioned in the Park Report, patient history is relevant only if "it is readily accessible to the pharmacist."³⁹ Based on my review of Walgreens's current pharmacy software system, I do not believe that the full patient history was as easily accessible as it should have been, especially given the time constraints and other pressures facing Walgreens pharmacists.

Nevertheless, I have undertaken further review of the patient history data associated with a significant number of additional prescriptions from the approximately 2,300 prescriptions I reviewed for the Park Report. This type of review is a common practice for California pharmacy consultants. Of the prescriptions I reviewed, less than 5% were associated with patient history data containing documentation sufficient in my opinion to resolve all the red flags raised by the prescription. This analysis does not materially alter my opinion that "Walgreens pharmacists


³⁷ Park Rep. 23.

³⁸ Park Rep. 23.

³⁹ Park Rep. 4.

failed to fulfill their corresponding responsibility by resolving and documenting resolution of red flags of diversion in the overwhelming majority of the prescriptions I reviewed.”⁴⁰

Respectfully submitted,

DocuSigned by:

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Elizabeth Akhpanyan Park, Pharm.D., APh
January 21, 2022

⁴⁰ Park Rep. 24.